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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/692,554

10/24/2003

Yasuyuki Kawashima

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1129

7590 05/29/2008
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EXAMINER

LEVKOVICH, NATALIA A

ART UNIT

PAPER NUMBER

1797

MAIL DATE

DELIVERY MODE

05/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/692,554	Applicant(s) KAWASHIMA ET AL.	
	Examiner NATALIA LEVKOVICH	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02/11/2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-46 is/are pending in the application.
- 4a) Of the above claim(s) 29-32, 36-38 and 45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-28, 33-35, 39-44 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/24/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/24/2003 and 10/05/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/05/2007 has been entered.

Election/Restrictions

2. Applicant's election of Species I (drawn to a sample analyzer comprising a controller configured to control the pipette washing unit and the washing solution supplier such that the pipette is washed with the washing solution when the analysis result is less than a predetermined value, and the pipette is washed with the acidic solution when the analysis result is equal to or greater than the predetermined value), made without traverse in the reply filed on 02/11/2008 is acknowledged. Accordingly, claims 29-32, 36-38 and 45 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions. Claims 26-28, 33-35, 39-44 and 46 are being considered on the merits, as follows.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims, as well as any structural detail that is essential for a proper understanding of the disclosed invention. Therefore, the detection unit connected to the sheath fluid supplier, to the sample preparation unit, to the controller, as well as to the other relevant components of the analyzer recited in the instant claims, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. Currently, the drawings show reflectors disposed on the side of the constant temperature bath, not of the reaction container.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner,

the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

4. The specification is objected to because of the attempt to incorporate subject matter into this application by reference to the Japanese patent publications 2000-321270, H5-1983, and H6-15772.

This incorporation is ineffective because incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 27-28 and 41-42 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The above listed claims recite a controller configured to control the pipette washing unit and the washing solution supplier such that the “pipette is washed with the washing solution when the analysis result is less than a predetermined value, and the pipette is washed with the acidic solution when the analysis result is equal to or greater than the predetermined value”.

Upon further reviewing the original specification, the Examiner found no support for this limitation.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 26-28, 33-35, 39-44 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being unclear for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 26, 35, 40 and 46 recite a controller “for calculating an analysis result from the detection signal obtained by the detection unit”. It is unclear whether or not this means that the controller is connected to the detection unit.

The claims also recite a sample preparation unit “for preparing a measured sample by diluting the sample supplied by the pipette”. It is not clear whether or not any means for measuring diluting liquids are intended.

In claim 27, with respect to the controller which “controls the pipette washing unit and the washing solution supplier such that the pipette is washed with the washing solution when the analysis result is less than a predetermined value, and the pipette is washed with the acidic solution when the analysis result is equal to or greater than the predetermined value, it is unclear whether or not any threshold setting and judging means are intended. See also claims 41-42.

Claim 28 recites the controller which “controls the pipette washing unit and the washing solution supplier such that the pipette is washed with the acidic solution after having been washed with the washing solution when the analysis result is equal to or greater than the predetermined value”. It is not clear whether or not the intended configuration implies some means which would ensure that the analysis results are initially kept below, and then above the predetermined value.

With respect to claim 35, it is unclear what structural features would configure the analyzer for analyzing bacteria. The same consideration applies to claim 40, with respect to conducting urine analysis.

Claim 44 recites a sheath fluid supplier “for supplying a sheath fluid to the detection unit to form a sheath flow; wherein the sheath fluid is used as the washing solution”. Does this limitation mean that the washing unit is incorporated into the detection unit? It is also not clear how the controller is related to the sheath fluid

supplier.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 26, 33-35, 39-40, 43-44 and 46 are rejected under 35 U.S.C. 102(b) as anticipated by Chupp et al. (US 5631165).

With respect to claims 26, 35, 40 and 46, Chupp discloses an automated analyzer for “distinguishing and differentiating cells in a sample”. The device comprises, as shown in Figures 3- 5, a sample processing area 110 [‘sample preparation unit’], aspiration probe 156 [‘pipette’] and “probe wash and dry unit” (not indexed). The system also includes “a dilution syringe coupled to the tubing network 182”, flow cells / impedance transducers 170, 174, 178 [‘detection units’], panel 114 [holder] accommodating cups 134, 144 capable of holding solutions, and a controller (Col.7, lines 20-30).

Referring to claims 33-32 and 39, note that the acidic solution and the sample are not positively claimed to be considered a part of the invention, and, therefore, are not accorded any patentable weight.

Regarding claims 43-44, Chupp discloses flow cell 170 with a laminar flowing

sample stream surrounded by diluent / sheath solution, the sheath solution coming from a supplier - (see (Col.17, lines 4-8),.

Double Patenting

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

12. Claims 26, 35, 40 and 46 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 6 of co-pending Application 11/ 729017. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to an analyzer

comprising a pipette ['specimen suction section'], sample preparation section unit, washing unit ['cleaning section'], detection unit ['measurement section'], container holder ['vessel placing section'], and a controller ['control means', 'judging means']. Thus, all the elements of the invention recited in the instant claims, are encompassed by claim 6 of 11/ 729017.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

13. Applicant's arguments filed 10/05/2007, have been fully considered but they are moot in view of new grounds of rejection.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalia Levkovich whose telephone number is 571-272-2462.

The examiner can normally be reached on Mon-Fri, 2 p.m.-10 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1797

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797